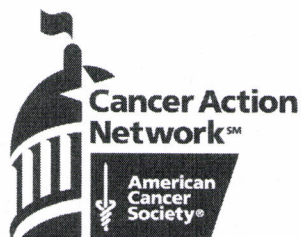


EXHIBIT NO. 4

DATE: 1/14/13

BILL NO. SB 55



Clinical Trials

The Costs of Patient Care

Numerous studies show that patient care in clinical trials costs approximately the same as care delivered in standard therapy. In some cases, because the third-party payer is not billed for the drug or treatment under investigation, care in a clinical trial can actually cost less than the care delivered in standard therapy.

Costs of patient care provided in a clinical trial are comparable to the costs of standard therapy.

Several studies on the costs of cancer clinical trials have been published in respected peer-reviewed publications.

- A pilot study conducted by the American Association of Cancer Institutes (AACI) showed that the total mean direct medical charges for patients enrolled in a clinical trial *were less than the charges for patients receiving standard therapy*.¹
- A December 2001 *Journal of Clinical Oncology* article similarly found that some clinical trials may actually result in *lower* patient care costs. In addition, in cases where trials resulted in modest increases in patient care costs, the authors concluded that these costs were justified by the benefits that clinical trials bring to all patients.²
- The Mayo Clinic has found that the cost of care for patients enrolled in clinical trials is often little more than for patients who received standard therapy.³
- Authors of a study conducted at Kaiser Permanente found that the cost of medical care for enrollees in clinical trials without bone marrow transplant were no higher than for patients who were not enrolled in a trial. Kaiser further states, "Kaiser has been participating in cancer clinical trials without substantial increases in the direct costs of medical care."⁴
- The most comprehensive study yet, published in 2003, also confirmed that there are only slightly higher patient-care costs associated with treating patients in cancer clinical trials compared to treating similar patients outside of trials.⁵

Some esteemed hospitals and universities have also conducted cost analysis studies.

- A study at Memorial Sloan-Kettering Cancer Center in New York City showed that the overall average cost of treating clinical trial patients was 17% *less* than treating patients receiving standard care.⁶
- A study conducted at the Karmanos Cancer Center in Detroit showed that the 6-month costs for treating advanced lung cancer were an average \$1,400 less for patients enrolled in a clinical trial.⁷

The Institute of Medicine has also concluded that the cost impact of providing coverage for routine patient care costs is likely to be "quite small."⁸ According to IOM, this is because:

- Reimbursement costs are limited to the cost of "standard care" which would be covered if the patient were not enrolled in the trial.
- Approximately 20% of adult cancer patients are eligible to participate in a clinical trial and approximately 3% of cancer patients actually do. Even if enrollment increased to the full 20% of eligible patients, it is unlikely that this would significantly impact overall costs to health plans.
- Through clinical trials, we will be able to also identify ineffective treatments, which could save health plans money and will benefit the nation as a whole.

Mandating coverage of routine care costs in clinical trials causes premiums to increase by less than 1%.

In general, mandates can potentially raise premiums. However, each mandate is different. Mandating that insurers pay for routine care costs in clinical trials has a minute effect on premiums. For instance, the Council for Affordable Health Insurance found that mandating coverage of routine care costs in clinical trials increased health insurance premiums by less 1%. There are several reasons for this.

- A small number of people enroll in clinical trials—roughly 3% of adult cancer patients.
- Routine care costs have been found to be, at most, marginally higher than care costs associated with standard treatment.

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